DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Ms. Becky Ronner
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

June 9, 2015

Re: K142559
Trade/Device Name: ELEVATE™ Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 8, 2015
Received: May 11, 2015

Dear Ms. Ronner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142559

Device Name
ELEVATE™ Spinal System

Indications for Use *(Describe)*
The ELEVATE™ Spinal System Expandable Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

MEDTRONIC Sofamor Danek
ELEVATE™ Spinal System

May 2015

I. Submitter

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Memphis, Tennessee 38132
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Contact: Becky Ronner
Senior Regulatory Affairs Specialist
Direct Telephone: (901)399-2757

Date Prepared: September 5, 2014

II. Device

Name of Device: ELEVATE™ Spinal System

Classification Names: Intervertebral Body Fusion Device
(21 CFR 888.3080)

Class: II

Product Code: MAX

III. Predicate Devices:

Globus CALIBER® K102293(Primary)
(S.E. January 5th, 2011)
CAPSTONE® Spinal System K073291 & K123027
(S.E. April 24th, 2008 & July 25th, 2013)
CRESCENT® Spinal System K094025
(S.E. April 26th, 2010)
Globus PATRIOT® K072970
(S.E. January 18th, 2008)
SOVEREIGN® Spinal System K122037
(S.E March 22nd, 2013)

Globus RISE® Spacer K113447
(S.E. January 26, 2012)
WAVE™ D Cage K083626 & K121333
(S.E. October 17, 2009 & S.E. June 29, 2012)
The predicates have not been subject to a design related recall.

IV. Description:

The ELEVATE™ Spinal System consists of polyetheretherketone (PEEK) with tantalum markers and titanium expandable cages of various length and heights, which can be surgically implanted between two lumbar or lumbarsacral vertebral bodies to give support and correction during lumbar intervertebral body fusion. The hollow geometry of the implants allows them to be packed with autogenous bone graft. This system also includes stainless steel and silicone instruments used to facilitate the implantation of the subject cages. Finally, the subject system includes case, trays, and lids used to package, ship and can be used to sterilize the non-sterile instruments in the subject system. The case, trays, and lids are manufactured from aluminum with either silicone or nylon coated brackets.

The ELEVATE™ Spinal System will be available in similar sizes as the predicate systems.

V. Indications for Use:

The ELEVATE™ Spinal System Expandable Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

VI. Comparison of Technological Characteristics with the Predicate Devices:

The ELEVATE™ Spinal System has the same fundamental technology, PEEK material with tantalum markers as the predicate devices. The predicate and subject devices are intended to be surgically implanted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar intervertebral body fusion. The subject and predicates implants include a bullet nose and were designed to contain graft material to facilitate a fusion between two vertebral bodies.

- Globus CALIBER® Spinal System (Primary)
- CAPSTONE® Spinal System
- CRESCENT® PEEK Spinal System
- Globus PATRIOT® Spinal System
- SOVEREIGN® Spinal System
- Globus RISE® Spacer
- WAVE™ D Cage

Additionally, like Globus CALIBER® Spinal System, the subject ELEVATE™ Spinal System is an expandable interbody device design and includes titanium alloy.

VII. Performance Data:

The following performance data were provided in support of substantial equivalence.

Biocompatibility

The biocompatibility evaluation for the ELEVATE™ Spinal System devices was conducted in accordance with FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" issued April, 23, 2013

The subject ELEVATE™ Spinal System implants are permanent implants and will be classified as permanent , >30 day body contact according to with FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The subject implants are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standards:

- ASTM F2026: Standard Specifications for Poletheretherketone Polymers for Surgical Implant Applications

- ASTM F 560: Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
- ASTM F136: Standard Specification for Wrought Ti-6Al-4V ELI Alloy for Surgical Implant

The ELEVATE™ Spinal System instruments are external communicating devices and are classified as limited, up to 24 hours of body contact according to with FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". These instruments are manufactured from the same medical grade stainless steel and silicone as the predicate devices in accordance with the following ASTM standards:

- ASTM F899 Standard Specification for Wrought Stainless Steels for Surgical Instruments
- ASTM A564 Standard Specification for Hot Rolled and Cold Finished Age Hardening Stainless Steel Bars and Shapes
- ASTM A693 Standard Specification for Precipitation-Hardening Stainless and Heat Resisting Steel Plate, Sheet and Strip

The case, trays, and lids used to for shipment and sterilization of instruments are manufactured from aluminum with either silicone or nylon coated brackets and are not patient contacting and do not require biocompatiblity testing.

The PEEK, tantalum, titanium alloy, medical grade stainless steel and silicone have a long history of safe and effective use in predicate spinal implants and instruments; based on this it was determined that biocompatibility testing is not required. No biocompatibility testing was conducted on the subject devices.

Mechanical Testing

In accordance with, Guidance for Industry and FDA Staff – Spinal System 510(k)'s", Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices.

Design verification testing was completed on the subject ELEVATE™ Spinal System in accordance with ASTM F2077-11 "Test Methods for Intervertebral Body Fusion Devices" and ASTM F2267-4 (2011) "Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression". The following testing was completed and tests met the predetermined acceptance criteria.

- Static Compression

- Compression Fatigue
- Static Compression-Shear
- Compression-Shear Fatigue
- Subsidence

Additional radiographic verification testing was completed demonstrating the substantial equalivence of the subject device to the predicates included in this submission.

In accordance with the FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" the subject ELEVATE™ Spinal System was evaluated for MR-safety in accordance with the following standards:

- ASTM F2052:2006 – "Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment"
- ASTM F2213:2006 – "Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment"
- ASTM F2119:2007(R13) – "Standard test method for evaluation of MR image artifacts from passive implants"
- ASTM F2182:2002a, 2011, 2011a – "Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging"

VIII. Conclusion:

Based on the risk analysis, test results, and additional supporting documentation provided in the pre-market notification, the subject ELEVATE™ Spinal System are as safe and effective as the following predicates:

- Globus CALIBER® K102293 (S.E. January 5th, 2011)
- CAPSTONE® Spinal System K073291 & K123027 (S.E. April 24th, 2008 & July 25th, 2013)
- CRESCENT® Spinal System K094025 (S.E. April 26th, 2010)
- Globus PATRIOT® K072970 (S.E. January 18th, 2008)
- SOVEREIGN® Spinal System K122037 (S.E March 22nd, 2013)
- Globus RISE® Spacer K113447 (S.E. January 26, 2012)
- WAVE™ D Cage K083626 & K121333 (S.E. October 17, 2009 & S.E. June 29, 2012)